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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,075	09/22/2003	Stephen A. Mamchur	4021.001	1250

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BALTIMORE, MD 21204

EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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01/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/668,075

Applicant(s)

MAMCHUR, STEPHEN A.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-122 is/are pending in the application.
- 4a) Of the above claim(s) 75-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27-74 and 81-122 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 27-122 are pending in this application.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 27-74 and 81-122, drawn to concentrated hormone composition, classified in class 424, subclass 401.
- II. Claims 75-80, drawn to kit comprising two separate containers, classified in class 428, subclass 34.1.

The inventions are independent or distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a concentrated hormone composition and a kit comprising separated containers. The two different inventions are not capable of use together because they have different modes of operation. The composition does not have to be used in a kit comprising two separated containers and the kit does not need to contain the claim invention.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Robert Gamson on January 17, 2008 a provisional election was made without traverse to prosecute the invention of Group I, claims 27-74 and 81-122. Affirmation of this election must be made by applicant in replying to this Office action. Claims 75-80 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Restriction Requirement

The restriction requirement in the office action dated September 12, 2007, is hereby withdrawn as applicant has amended claim 81 to depend from claim 40 which is part of the group I.

Claim Objections

Claims 94-100 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 94-100 have not been further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-32, 35-43, 47-50, 60-63, 65-74, 110-115 and 118-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonella (US 5,665,377) in view of Dal Farra et al. (US 2005/0129779).

Applicant claims a concentrated hormone composition comprising at least one hormone and at least solvent.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Gonella discloses a composition comprising a mixture of estradiol together with propylene glycol (claim 3, col. 4). Column 2, lines 28-30 discloses that the composition

may contain an appropriate mixture of estradiol or a combination of estradiol and progestin. Column 3, lines 13-35 discloses a method of making the composition comprising dissolving the drug in a solvent followed by a mixing step and then heating the composition. The final composition can then be stored in closed containers to protect it from moisture and air.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Gonella does not disclose the claimed concentration of the hormone as claimed or the solvent is a mixture of propylene and ethoxy diglycol. It is for this that Dal Farra et al. is joined.

Dal Farra et al. disclose in ¶ [0043] that the pharmaceutical agent is solubilized in a pharmaceutically acceptable solvent comprising water, ethanol, propylene glycol, ethoxy diglycol or mixtures thereof.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It is the position of the examiner that the determination of the hormone concentration or solvent mixture would have been within the skill of the artisan. This determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific concentrations of the hormone or the

solvent mixture employed by applicant in the instant case. Dal Farra et al. teach that in the formulation of pharmaceutical compositions a mixture of solvents i.e. water, ethanol, propylene glycol, ethoxy diglycol, etc. can be employed.

Claims 27-32, 35, 36, 39-53, 60-64, 81-91 and 102-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. (2002/0173669).

Applicant claims a concentrated hormone composition comprising at least one hormone selected from estriol, estradiol and combinations thereof and at least solvent.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Schultz et al. disclose a steroid hormone composition comprising estrogen and progestin [¶0014]. ¶0015 disclose that the composition can comprise an excipient such as lactose and ¶0038 discloses that the composition can contain disintegrants, lubricants and colorants.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Schultz et al. do not disclose the claimed concentration of the hormone as claimed or the combination of different estrogen-based hormones.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It is the position of the examiner that the determination of the hormone concentration would have been within the skill of the artisan. This determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific concentrations of the hormone employed by applicant in the instant case. It would have also been obvious to one of ordinary skill in the art to use a combination of different estrogen-based hormones for the purpose of maximizing the delivery of estrogen to the patient.

Claims 27-32, 35, 36, 39, 54-59, 116 and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosairo-Jansen et al. (2002/0173669).

Applicant claims a concentrated hormone composition comprising testosterone and at least solvent.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Example 2, ¶0095 of Rosario-Jansen et al. disclose a topical administration of testosterone and a carrier vehicle.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Rosario-Jansen et al. do not disclose the claimed concentration of the hormone as claimed.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It is the position of the examiner that the determination of the hormone concentration would have been within the skill of the artisan. This determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific concentrations of the hormone employed by applicant in the instant case.

Claims 27-32, 35, 36, 39, 60-64, 118 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson (US 6,303,132).

Applicant claims a concentrated hormone composition comprising testosterone and at least solvent.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Nelson discloses a topical progesterone composition comprising progesterone and emu oil (abstract).

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Nelson does not disclose the claimed concentration of the hormone as claimed.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It is the position of the examiner that the determination of the hormone concentration would have been within the skill of the artisan. This determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific concentrations of the hormone employed by applicant in the instant case.

Conclusion

Claims 27-74 and 81-122 are rejected.

Claims 75-80 are withdrawn from examination as directed to non-elected claims.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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